DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
Central Region
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Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
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February 22, 2007

WARNING LETTER
CIN-07-32218-12

VIA FEDERAL EXPRESS

Joseph M. Hogan
President and CEO
GE Healthcare Technologies
3200 N. Grandview Boulevard
W-701
Waukesha, WI 53188

Dear Mr. Hogan:

During an inspection of your medical device manufacturing facility (USA Instruments) located at 1515 Danner Drive, Aurora, OH from 11/6/2006 – 12/19/2006, a Consumer Safety Officer (CSO) from the United States Food and Drug Administration (FDA) determined that your firm manufactures coils used in magnetic resonance imaging systems and breast biopsy plates. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease.

This inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (C.F.R.), Part 820. We received a response from Anthony deShazer, President & General Manager USA Instruments and Roger B. Smith, Vice President Quality Assurance & Regulatory Affairs Manager USA Instruments dated January 14, 2007 concerning our CSO's observations noted on the Form FDA-483, Inspectional Observations, that was issued to Mr. deShazer. We address the response below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. You failed to assure that only those devices that are approved for release are distributed. For example, you shipped product to customers prior to completion of the sterilization process validation. For example, you shipped breast biopsy plates sterilized by [redacted] prior to: a) completing the package integrity testing and b) approving the sterilization process. [21 CFR 820.160(a) and 21 CFR 820.75(a).] Your response to this portion of the observation appears adequate.

Additionally, you shipped product to customers prior to verifying/validating the device design. For example, 1.5 T, Head, Neck and Spine Coils were released for sale in May 2006, and you did not complete the device's design verification and validation prior to release. [21 CFR 820.160(a) and 21 CFR 820.30(f) and (g)]. Your response to this observation appears to be incomplete. As noted above, you distributed these coils prior to the completion of the validation. Your "Preventive" action does not indicate how you will prevent devices with incomplete design validation from being released in the future.

2. You failed to fully document your validation activities for breast biopsy plates. For example, for your previous contract sterilizer ([redacted]): a) there is no evidence of acceptance of revalidation activities since 2000 and b) there is no documentation of the acceptance of the sterilization protocol or results. [21 CFR 820.75(a)] We acknowledge that you are recalling this product and that you have addressed this issue in the response letter. The response appears to be adequate.

3. You failed to verify or validate corrective actions taken in response to CAPA 69 dated 3/29/2004. You identified soldering issues as one of the top three manufacturing defects. As part of the corrective action you conducted off-site training in 2005 to improve solder skills. This was two-part training with a written exam and a hands-on practical test. Nine out of 17 (53%) of training records that we reviewed for solder skills were incomplete, missing, or showed failing results for that exam. In February 2006, CAPA 352 documents that solder defects are still a major issue at your firm. [21 CFR 820.100(a)(4)] Your response does not address how you will assure that your corrective actions actually correct the problems that you identify.

4. Your device history records for the eight channel Body Array Coil failed to include complete acceptance records that demonstrate the device is manufactured in accordance with the device master record. For example: a) DHR for serial number [redacted] shows an out of specification sensitivity measurement (used in tuning coils) of [redacted] where the requirement is [redacted]. There is no documentation of this discrepancy in the DHR; b) DHR for serial number [redacted] does not show documentation of testing for nine of the final inspection tests on the coil, yet, the final inspectional checklist received a final approval signature. [21 CFR 820.184(d)] Your response to this item appears to be adequate.

5. You failed to investigate the possible failure of devices to meet any of their specifications when necessary. For example, you did not document the investigation of the following closed complaints: Complaint 13070082 received on 3/3/06 involved Knee Coil early life failure and there is no documentation of the investigation of this coil. Additionally, Complaint 13068036 received on 2/16/06 involved the potential excessive warming of Head Coil, and the root cause is not clearly documented nor was the manufacturing process investigated as stated in the complaint file. [21 CFR 820.198(c)] It is unclear from your response how you will prevent the premature closure of complaints before investigations are completed. Please elaborate on this response.

6. You failed to process your complaints in a uniform and timely manner. For example: your current complaint procedure (P8.5.2-01, Rev 12, 8/22/06) states that PSRs (safety complaints) over 45 days and PQRs (quality reports) open over 90 days are overdue. You currently have at

least 12 complaints that are beyond these time frames. Three examples include: a) Complaint 13051407 was created on 8/25/05 due to Torso Coil quality and reliability issues, b) Complaint 13055811 was created on 10/20/05 due to body array coil capacitor failures, and c) Complaint 13056439 was created on 10/28/05 due to distorted picture of phantom scans using a Torso Coil. [21 CFR 820.198(a)(1)]. We acknowledge that you have stated that you are devoting more resources to this area of your operation. Please update the status of this corrective action.

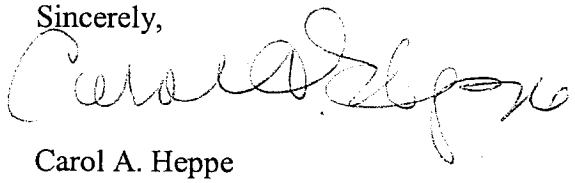
You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction and/or civil money penalties. Also, federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pre-market applications for Class III devices to which the Quality System regulation deficiencies are reasonably related will be approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be granted until the violations related to the subject devices have been corrected.

Please notify this office within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations or similar violations from occurring again. Please provide updates on the progress of your unfinished corrective actions. Include documentation of the corrective action you have taken. If your corrective actions will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Mr. Stephen J. Rabe, Compliance Officer, Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237. If you have any questions concerning the contents of this letter, you may contact Mr. Rabe at (513) 679-2700, ext. 163, or you may forward a facsimile to him at (513) 679-2773.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Form FDA-483, Inspectional Observations, issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

Sincerely,



Carol A. Heppe
District Director
Cincinnati District